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10/632,117	07/31/2003	Hilda Elizabeth Smith	2183-6055US	5350

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
10/03/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/632,117	SMITH, HILDA ELIZABETH	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,9, 11-15 and 21-27* is/are pending in the application.

4a) Of the above claim(s) *1,6 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed March 27, 2007 has been entered. Claim 11 has been amended. Claims 2-5, 8, 10 and 16-20 have been cancelled. Claims 1, 6-7 and 9 have been withdrawn from consideration. Claims 21-27 are newly added. Claims 11-15 and 21-27 are under consideration in this office action.

Withdrawal of Rejections

2. The rejection of claims 11-12 and 15 under 35 U.S.C. 102(b) as being anticipated by 1997/1998 Stratagene catalog (page 118, 1997/1998) has been withdrawn in view of applicants amendments and arguments.

Response to Arguments

3. Applicant's arguments filed March 27, 2007 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11-15 and 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 11 is drawn to an isolated or recombinant nucleic acid molecule comprising: a nucleotide sequence of *Streptococcus* origin; wherein the nucleotide sequence hybridizes to the full length of nucleotide sequence of SEQ ID NO:37; at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2. Claim 21 is drawn to an isolated or recombinant nucleic acid molecule comprising: a nucleotide sequence of *Streptococcus* origin wherein the nucleotide sequence hybridizes to the full length nucleotide sequence of SEQ ID NO:37 at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2 wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C.

No information, beyond the characterization of a nucleotide sequence of *Streptococus* origin and the ability to hybridize to the full length of SEQ ID NO:37 has been provided, which would indicate that applicants had possession of the claimed genus of a nucleotide sequence of *Streptococus* origin. The specification does not contain any disclosure of the structure of all the mutants or variants of any nucleotide sequences within the scope of the claimed genus. The genus of a nucleotide sequence

claimed is a large variable genus including mutants and variants, which can have wide variety of structures. The specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

With respect to the claims, the specification does not place any structure, chemical functional limitations on the polynucleotide probe per se. It is noted that the nucleic acid sequence that hybridizes to SEQ ID NO:37. The recitation of a nucleic acid sequence does not convey a common structure or function. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the nucleic acid sequence. Structural features that could distinguish molecules in the genus from others in the class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. The specification and claims lack sufficient written description of the generically claimed hybridizing nucleotide sequence which is defined by its function, i.e., to hybridize under the recited stringency conditions and remained hybridized. While the description of the ability of the claimed nucleic acid molecule to hybridize, may describe the molecule's function, it does not describe the nucleotide sequence itself. The hybridization distinction is purely a functional distinction which is insufficient.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

The nucleic acid molecule comprising one or more nucleic acids is defined by its activity of function, i.e., the ability to hybridize to a nucleotide sequence of SEQ ID NO:37. While the description of the ability of the claimed nucleic acid molecule which hybridizes may generically describe the nucleic acid molecule's function, it does not describe the nucleic acid molecule itself. The hybridization capability distinction is a purely functional distinction. Thus, a description of the nucleic acid molecule by what it does, such as hybridizing to a nucleotide sequence of SEQ ID NO:37 is insufficient. Since the disclosure fails to describe the common attributes or structural characteristics that identify the members of the genus, and because the genus of nucleic acid

molecules of is highly variable, the function of hybridization alone is insufficient to describe the genus of nucleic acid molecules.

An adequate description requires more than a mere statement that it is part of the invention. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Encoding distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant claims describe a nucleic acid molecule described by its function i.e., hybridization, however this description does not describe the claimed nucleic acid molecules themselves. See also, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of the claimed polypeptides. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Response to Arguments

5. Applicant's arguments filed March 27, 2007 have been fully considered but they are not persuasive.

Applicants' argue that the structure of the isolated or recombinant nucleic acid molecules would be clear to one of ordinary skill in the art based on the description SEQ ID NO:37. While is clear that the SEQ ID NO: 37 has been identified, applicants still have not described the isolated or recombinant nucleotide sequence which may encompass small fragments that are capable of hybridizing to the full length of a nucleotide sequence SEQ ID NO: 37. Thus applicants were not in possession of the isolated or recombinant nucleic acid molecules which hybridize to SEQ ID NO:37. There are no experiments which show the isolation or recombinant making of a nucleic acid molecule which is capable of hybridizing as instantly claimed. There are no vectors, host cells or compositions which comprise the isolated or recombinant nucleic acid molecule fragments. It is noted that possession of SEQ ID NO: 37 does not equate

to possession of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising: a nucleotide sequence capable of hybridizing to the full length of SEQ ID NO: 37 which hybridizes at the recited conditions. Thus, Applicants arguments are not found persuasive.

As previously stated, the specification does not place any structure, chemical or absolute functional limitations on the nucleic acid molecule per se. The recitation of a nucleic acid molecule does not convey a common structure or function. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the nucleic acid molecules. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. The skilled artisan cannot envision the detailed structure of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin as instantly recited, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Therefore, applicants' arguments were not persuasive and the rejection is maintained.

Enablement Rejection

6. In this regard, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). These factors are considered when determining whether there is sufficient evidence to

support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

7. Claims 11-15 and 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claim 11 is drawn to an isolated or recombinant nucleic acid molecule comprising: a nucleotide sequence of *Streptococcus* origin; wherein the nucleotide sequence hybridizes to the full length of nucleotide sequence of SEQ ID NO:37; at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2. Claim 21 is drawn to an isolated or recombinant nucleic acid molecule comprising: a nucleotide sequence of *Streptococcus* origin wherein the nucleotide sequence hybridizes to the full length nucleotide sequence of SEQ ID NO:37

at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2 wherein the nucleic acid molecule remains hybridized after washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 5% sodium dodecyl sulphate for 30 minutes at 65°C and; washing twice with a buffer containing 40 mM sodium phosphate (pH 7.2), 1 mM EDTA and 1% sodium dodecyl sulphate for 30 minutes at 65°C.

The specification fails to identify an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin wherein the nucleotide sequence hybridizes to the full length of nucleotide sequence of SEQ ID NO:37; at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2. The specification does not support the broad scope of claims 11 and 21 because the specification does not establish: (A) regions of s nucleotide sequence; (B) the general tolerance of the nucleotide sequence to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. While the specification provides support for SEQ ID NO:37, the specification is silent with regards to providing guidance on a nucleotide sequence of *Streptococcus* origin wherein the nucleotide sequence hybridizes to the full length of nucleotide sequence of SEQ ID NO:37.

In view of the broad the breath of the claims; the unpredictability of the art; the lack of direction or guidance presented; the absence of working examples; and the high

quantity of experimentation necessary; there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue despite support for SEQ ID NO:37.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of nucleotide sequences with an enormous number of nucleic acid modifications within SEQ ID NO: 37. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. USPQ2nd 1400 (Fed. Cir, 1988). See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). Accordingly, one of skill in the art would be required to perform undue experimentation to use any nucleic acid at any location to produce such a nucleic acid molecule. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Response to Arguments

8. The enablement rejection of claims 11-15 and 21-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicants' assert that paragraph [0066] describes using SEQ ID NO:37 as a probe to identity a chromosomal DNA of *S. suis*. However this section fails to provide an

enabling disclosure drawn to an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising: a nucleotide sequence capable of hybridizing to the full length of the nucleotide sequence of SEQ ID NO: 37 at the instantly recited conditions. There is no teaching of isolated or recombinant nucleic acid molecules from *Streptococcus agalactiae, S. bovis, S. equi, S. pneumoniae, S. pyogenes, S. thermophilus* or *Viridans Streptococci* hybridizing at the recited conditions. There is no disclosure of any of these nucleic acid molecules being comprised within a vector, host cell or composition. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin.

Applicants' also urge that SEQ ID NO:37 is not only capable of hybridizing with nucleic acids of *S. suis* serotype 2 but with a large number of *S. suis* strains of other serotypes. Applicants' have pointed to paragraph [0079] as providing a working example of an isolated or recombinant nucleic acid molecule, and state that one of ordinary skill in the art would be able to make and use the instantly claimed isolated or recombinant nucleic acid molecule without undue experimentation. However this paragraph is drawn to cloning the *S. suis* fibronectin binding protein. There is no teaching of hybridization occurring at 65°C in a buffer having 0.5M sodium phosphate, 1mM EDTA and 7% sodium dodecyl sulphate at a pH of 7.2. There is no teaching that the claimed nucleotide sequence hybridized to the full length of SEQ ID NO:37. Therefore, the specification fails to enable an isolated or recombinant nucleic acid

molecule of a *Streptococcus* origin as instantly claimed because the specification fails to teach the identity of such sequences. Thus, Applicants arguments are not found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 11-15 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. The rejection is on the grounds that claim 11 omits the essential wash criteria.

Applicants' assert that there is no need to include additional washing steps. However, the specification teaches that stringent wash conditions are sequence-dependant and will be different in different circumstances. As such, the claim is dependant upon specific conditions that are not recited in the claims and specification fails to define the metes and bounds of the claim language. Therefore one skilled in the would not be readily apprised as to the metes and bounds of the hybridizing nucleic acids. The claim language is not defined, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The language is a term of degree and based upon parameters that are not defined in the specification or the claims.

New Grounds of Claim Objections

10. Claim 21 is objected to because of the following informalities:

a) Claim 21, lines 5 has a period in the middle the sentence, "pH of 7.2. wherein" however the period should be removed. Appropriate correction is required.

Conclusion

11. No claims allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 6, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER